Remarks

This communication is responsive to the non-final Office action mailed July 26, 2007. Prior to entry of this amendment, claims 1-20, 25-30, 45 and 46 are pending and under consideration in the present application.

Claims 1, 8, 20, and 27 have been amended. Support for the amendment to the claims can be found in the specification, for example, at page 20, lines 19-21 (claim 1); and page 20, lines 19-21 (claim 20). Claim 8 has been amended to depend from claim 1 rather than claim 7. Claim 27 has been amended to correct a typographical error.

Claims 7, 9, 10, 12-19, 28-29, and 45-46 have been cancelled.

New claims 58-64 have been presented for examination. Support for new claims 58-64 can be found in the specification, for example, at page 21, lines 11-26 and in claims 2-5 and 11-12.

Upon entry of this amendment, claims 1-8, 11, 20, 27, 30, and 58-64 will be pending and under examination in this application.

Claim Rejections - 35 U.S.C. § 112

Claims 5, 19 and 29 stand rejected under 35 USC 112, second paragraph.

Applicants respectfully traverse.

With respect to claim 5, the Office Action states that there is insufficient antecedent basis in the claim for the limitation "wherein the disease state to be treated is selected from the group consisting of ocular neovascularization, ocular inflammation and retinal degernation". Applicant disagrees with the position taken in the Office Action. First, it should be noted that claim 5 states "...wherein *a* disease state to be treated...", not "...wherein *the* disease state to be treated..." as stated in the Office Action (emphasis added). The remaining portion of claim 5 properly sets out a Markush group including the elements of ocular neovascularization, ocular inflammation, and retinal degeneration. Since the term "disease state" is properly introduced with the term "a", not "the", there is no error in providing antecedent basis for the term "disease state" in claim 5.

The remaining claims (19 and 29) rejected under 35 USC 112, second paragraph, have been cancelled.

In view of the foregoing, the rejection of claim 5 under 35 USC 112, second paragraph, should be withdrawn.

Claim Rejections - 35 U.S.C. §102

Claims 1-4, 6, 7, 9-12, 14-18, 20, 25-30, 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (US 5,869,079).

Applicants respectfully traverse.

Wong et al. relates to compositions and methods for biodegradable implants that are formulated to provide a controlled, sustained drug release. The release rate is modulated by combining in the implant hydrophobic and hydrophilic agents. The release modulator may act to accelerate or retard the rate of release. Wong et al. teaches that suitable sites include the anterior chamber, posterior chamber, vitreous cavity, suprachoroidal space, subconjunctivea, episcleral, intracorneal, epicorneal and sclera.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131. The identical invention must be shown in as complete detail as is contained in the claim. MPEP 2131 citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9USPQ2d 1913, 1920 (Fed Cir. 1989).

With respect to claim 1, the Wong et al. reference fails to describe, either expressly or inherently, a method for administering a therapeutic medium to a posterior segment of an eye, the method comprising the step of: instilling the therapeutic medium sub-retinally; wherein the step of instilling comprises injecting a solution including the therapeutic medium in the sub-retinal space. With respect to claim 20, the Wong et al. reference fails to describe, either expressly or inherently, a method for treating an eye, comprising the step of: administering a therapeutic medium to a posterior segment of an eye sub-retinally; wherein said administering comprises: (a) forming a sub-retinal space; and (b) injecting a solution including the therapeutic medium in the sub-retinal space. Wong et al. is concerned with the implantation of solid biodegradable implants and does disclose the use of a solution including the therapeutic medium to treat an eye.

Since Wong et al. fails to disclose all elements of the claims, either expressly or inherently, it does not anticipate Applicants invention of claims 1 and 20.

Claims 1, 3-5, 7, 9-12, 14-20, 25-29 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes et al. (US 5,869,079).

Applicants respectfully traverse.

The Office Action states that claims 1, 3-5, 7, 9-12, 14-20, 25-29 and 45 are rejected under 35 USC 102(b) as being anticipated by "Hughes et al. (US 5,869,079)." Applicants point out that no U.S. patent identified as "Huges et al. (US 5,869,079)" exists. U.S. Patent No. 5,869,079 was invented by Wong et al. In addition, there is no patent having the inventive entity "Hughes et al." that is of record in this application in either a form PTO-1449 or form PTO-892. Applicant respectfully requests clarification/correction of this rejection in a second non-final Office Action.

Going forward, assuming that the Examiner intended to cite US 5,962,027 (Hughes), it is submitted that this reference does not anticipate the amended claims. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131. The identical invention must be shown in as complete detail as is contained in the claim. MPEP 2131 citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9USPQ2d 1913.

Hughes (US 5,962,027) relates to a method for the preparation of a graft for transplantation into the subretinal area of a host eye. With respect to claim 1, the Hughes reference fails to describe, either expressly or inherently, a method for administering a therapeutic medium to a posterior segment of an eye, the method comprising the step of: instilling the therapeutic medium sub-retinally; wherein the step of instilling comprises injecting a solution including the therapeutic medium in the sub-retinal space. With respect to claim 20, the Hughes reference fails to describe, either expressly or inherently, a method for treating an eye, comprising the step of: administering a therapeutic medium to a posterior segment of an eye sub-retinally; wherein said administering comprises: (a) forming a sub-retinal space; and (b) injecting a solution including the therapeutic medium in the sub-retinal space.

In view of the foregoing, it is submitted that the rejection under 35 U.S.C. §102(b) based on Hughes (US 5,962,027) has been overcome and should be withdrawn. The dependent claims are also not anticipated for at least the same reasons.

Claim Rejections - 35 U.S.C. §103

Claims 5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 5,869,079) as applied to claims 1-4, 6, 7, 9-12, 14-18, 20, 25-30, 45 and 46 above in view of Hughes et al. (US 5,869,079) as applied to claims 1, 3-5, 7, 9-20, 25-29 and 45 above.

Applicants again point out to the Examiner that no U.S. patent identified as "Hughes et al. (US 5,869,079)" exists. Applicant respectfully requests clarification/correction of this rejection in a second non-final Office Action.

Notwithstanding the defective rejection, claim 5 is allowable because it is a dependent claim which depends directly from claim 1. Claim 1 is patentable for the reasons argued herein. Claim 5, which includes all of the limitations of claim 1, should be patentable for at least the same reasons. Claim 19 has been cancelled.

In view of the foregoing, it is submitted that the rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Wong et al. in view of Hughes (US 5,962,027) has been overcome and should be withdrawn.

Claims 1, 7, 8 and 11-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Louis (US 5,641,750) in view of Wong et al. (US 5,869,079) and further view of Hughes et al. (US 5,869,079).

Applicants again remind the Examiner that no U.S. patent identified as "Hughes et al. (US 5,869,079)" exists. Applicant respectfully requests clarification/correction of this rejection in a second non-final Office Action.

Louis relates to a method for treating vision loss due to photoreceptor degeneration by administering a therapeutically effective amount of glial cell line-derived neurotrophic factor (GDNF) protein product. According to one aspect of the invention, methods are provided for treating vision loss due to photoreceptor degeneration by

administering a therapeutically effective amount of GDNF protein product. It is contemplated that such GDNF protein products would include a GDNF protein such as that depicted by the amino acid sequence set forth in SEQ ID NO:1, as well as variants and derivatives thereof. It is reported that administration of GDNF protein product promotes the survival and regeneration of damaged photoreceptor neurons, which are the main population of neurons damaged in retinal degenerations leading to blindness.

According to Louis, GDNF protein product may be administered intraocularly at a dose between about 0.001 mg/day and 10 mg/day, preferably at a dose between about 0.01 mg/day and 1 mg/day, and most preferably at a dose between about 0.1 mg/day and 0.5 mg/day. It is reported that the delivery means for the administration of a GDNF protein product in the treatment of ophthalmic conditions or diseases may advantageously involve topical formulations, ocular inserts, ocular injection, ocular implants, cell therapy or gene therapy.

As admitted in the Office Action, Louis does not teach administration to the posterior segment of the eye by instilling a therapeutic medium sub-retinally. The Office Action relies upon Wong and Hughes to cure the deficiency in Louis. As discussed hereinabove, Wong et al. relates to compositions and methods for biodegradable implants that are formulated to provide a controlled, sustained drug release. The release rate is modulated by combining in the implant hydrophobic and hydrophilic agents. Wong et al. does not teach or suggest injecting a solution including a therapeutic medium in the sub-retinal space. Hughes (US 5,962,027) relates to a method for the preparation of a graft for transplantation into the subretinal area of a host eye. As with Wong et al., Hughes does not teach or suggest injecting a solution including a therapeutic medium into the sub-retinal space. There is no motivation to combine the teachings of Louis with Wong et al. or Hughes. Louis explicitly reports that the delivery means include topical formulations, ocular inserts, ocular injection, ocular implants, cell therapy or gene therapy. There is no reason to modify the delivery means that are specifically set forth in Louis using the teaching of Wong et al. and/or Hughes which relate to solid implants and grafts, respectively.

In view of the foregoing, it is submitted that the rejection over Louis in view of Wong et al. and further view of Hughes (US 5,962,027) has been overcome and should be withdrawn.

Conclusion

It is respectfully submitted that the claims and the present application are now in condition for allowance. Approval of the application and allowance of the claims is earnestly solicited. In the event that a phone conference between the Examiner and the undersigned would help resolve any remaining issues in the application, the Examiner is invited to contact undersigned at (651) 275-9830.

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Respectfully Submitted,

By: _____

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